REMARKS

Claims 1-26 are pending in the application. In the Office Action at hand, those claims are rejected.

In particular, Claims 1-3, 7-17 and 20-26 are rejected under 35 USC §102(e) as being anticipated by Yang. In addition, Claims 5, 6 and 19 are rejected under 35 U.S.C. §103(a) as being unpatentable over Yang and Herweck (U.S. 5,411,550). Furthermore, Claims 4 and 18 are rejected under Section 103(a) as being unpatentable over Yang and Sullivan. In response to the Section 102(e) and 103(a) rejections, the Applicant respectfully submits that Claims 1-6, 8, 9, 11-19 and 21-26 as amended, are not anticipated or obvious in view of Yang, Herweck and Sullivan. Reconsideration is respectfully requested.

Claim 1, as amended, recites a vascular graft device including a semi permeable inner wall surrounding a passage. A nonpermeable outer wall surrounds the inner wall. The graft device can be configured for access by a needle and is longitudinally bendable and has first and second ends. The inner and outer walls are sealed to each other at the first and second ends forming an annular gap between the inner and outer walls. The first and second ends each are configured for suturing to at least one blood vessel. A biological agent can be disposed between the inner and outer walls for release through the inner wall radially inwardly in a circular fashion at least near the first and second ends for treating suture points joining the at least one blood vessel and the first and second ends.

Claim 14, as amended, also recites a vascular graft device, Claim 15, as amended, recites a vascular graft device that includes an inner graft member, Claim 16, as amended, is a method claim that generally parallels Claim 1, as amended, and Claim 26, as amended, recites a method of limiting occlusion in a vascular graft.

Claims 1, 16 and 26 have been amended to recite "the graft device being configured for access by a needle and being longitudinally bendable and having first and second ends, the inner and outer walls being sealed to each other at the first and second ends, forming an annular gap between the inner and outer walls, the first and second ends each being configured for suturing to at least one blood vessel", and a biological agent disposed between the inner and outer walls for release through the inner wall "radially inwardly in a circular fashion at least near the first and

second ends for treating suture points joining the at least one blood vessel at the first and second ends," Claim 14 has been amended to recite " the graft device being configured for access by a needle and being longitudinally flexible and the first and second ends of the graft device each being configured for suturing to at least one blood vessel", and a "biological agent disposed between the inner and outer walls at least near the first and second ends for release through the inner wall radially inwardly in a circular fashion at least near the first and second ends for treating suture points joining the at least one blood vessel at the first and second ends," and Claim 15 has been amended to recite "an inner graft member positioned within the passage of the inner wall, the inner graft member having first and second ends extending beyond the inner and outer walls for suturing to at least one blood vessel." Support for these amendments is found at least in FIGs. 1-4 as well as on page 3, line 19 through page 5, line 28 of the Specification as originally filed. In addition, Claims 8 and 11 have been amended to be dependent upon Claim 1, and Claims 21 and 23 have been amended to be dependent upon Claim 16.

In embodiments of the invention, of Claim 1, as amended, biological agents, such as drugs for resisting occlusion of the vascular graft device and/or the blood vessels at the suture points, can be efficiently delivered. The inner wall is permeable so that the biological agent can be released radially inwardly in a circular fashion, at least near the first and second ends for treating the suture points and the interior of the vascular graft device. Since suture points with blood vessels are typically circular, such circular release of the biological agents can provide efficient targeted delivery to the suture points. In addition, the outer wall can be impermeable and sealed to the inner wall at the first and second ends which can permit unwanted release of the biological agent radially outwardly from the vascular graft device, or axially from the ends. The vascular graft device can be configured to be accessed by a needle, for example, for dialysis. In addition, by being longitudinally bendable, the vascular graft device can be sutured between two blood vessels in a bent configuration such as in a "U" configuration as seen in FIG. 1, which can limit stress or tearing at the suture points when the vascular graft device is accessed by a needle due to the extra slack provided by the bent configuration.

In contrast, Yang discloses in FIG. 1 a wire mesh stent 102 having a cover 104 with layers 108 and 110, defining a chamber 106 therebetween. The chamber 106 holds drugs to be released through one or both layers 108 and 110. The layers 108 and 110 of the cover 104 can

be secured together and the ends 103 can be sutured 105 to the ends 120, 122 of the stent 102 for securement of the components relative to each other.

Portions of the stent extend beyond the ends 103, making the ends 103 unsuitable for suturing to blood vessels. In addition, the stent 102 is not designed to be longitudinally bent, for example, in a "U" configuration, but instead is designed to expand in a blood vessel in a longitudinally straight manner. The stent 102 being wire mesh is also not suitable for penetration by a needle, for example, for dialysis. Furthermore, a straight configuration is not suitable for suturing between two blood vessels because forcing a needle into such a straight configuration can push it laterally sideways, which can increase stress on the suture points and the likelihood of tearing the sutures since there is no slack provided by a straight configuration.

Accordingly, Claims 1-3, 8, 9, 11-17 and 21-26, as amended, are not anticipated by Yang since Yang does not teach or suggest "the graft device being configured for access by a needle and being longitudinally bendable and having first and second ends, the inner and outer walls being sealed to each other at the first and second ends, forming an annular gap between the inner and outer walls, the first and second ends each being configured for suturing to at least one blood vessel; and a biological agent disposed between the inner and outer walls for release through the inner wall radially inwardly in a circular fashion at least near the first and second ends for treating suture points joining the at least one blood vessel at the first and second ends", as recited in Claim 1, as amended, and similarly in Claims 16 and 26, as amended, or "the graft device being configured for access by a needle and being longitudinally flexible and the first and second ends of the graft device each being configured for suturing to at least one blood vessel; and a biological agent disposed between the inner and outer walls at least near the first and second ends for release through the inner wall radially inwardly in a circular fashion at least near the first and second ends for treating suture points joining the at least one blood vessel at the first and second ends", as recited in Claim 14, as amended, or "an inner graft member positioned within the passage of the inner wall, the inner graft member having first and second ends extending beyond the inner and outer walls for suturing to at least one blood vessel", as recited in Claim 15, as amended. Therefore, Claims 1-3, 8, 9, 11-17 and 21-26, as amended, are in condition for allowance. Reconsideration is respectfully requested.

Herweck discloses in FIG. 14 a vascular graft having a semi permeable wall 14 laterally separating the first lumen 12 from the second lumen 12'. The lumen can be seeded with cells, for example, endothelial cells.

Accordingly, Claims 5, 6 and 19 are not obvious in view of Yang and Herweck since neither reference, alone or in combination, teach or suggest "the graft device being configured for access by a needle and being longitudinally bendable and having first and second ends, the inner and outer walls being sealed to each other at the first and second ends, forming an annular gap between the inner and outer walls, the first and second ends each being configured for suturing to at least one blood vessel; and a biological agent disposed between the inner and outer walls for release through the inner wall radially inwardly in a circular fashion at least near the first and second ends for treating suture points joining the at least one blood vessel at the first and second ends", as recited in base Claim 1, as amended, and similarly in base Claim 16, as amended. Therefore, Claims 5, 6 and 19 are in condition for allowance. Reconsideration is respectfully requested.

Sullivan discloses in FIGs. 1 and 2, a vascular bypass graft having an inner vascular graft 12 and a knitted outer sleeve 14, forming a narrow annulus 16 that can be filled with a bioactive compound, including microspheres. The graft 12 is sutured to the blood vessels first and then the sleeve 14 is sutured in place. The knitted sleeve 14 has pores that are permeable, and the ends of the graft 12 and sleeve are not sealed to each other. Column 5, line 66 through column 6, line 3 describes leakage through the pores of the sleeve 14 or out the ends of the annulus 16. An opening or nick 15 can be made in the sleeve 14 allowing an injector 30 to inject the bioactive compound in the annulus 16. The opening 15 then must be sutured closed. Consequently, it can be seen that the bypass graft in Sullivan is not configured for access by a needle, for example, for dialysis.

Accordingly, Claims 4 and 18 are not obvious in view of Yang and Sullivan, since neither reference, alone or in combination, teach or suggest "the graft device being configured for access by a needle and being longitudinally bendable and having first and second ends, the inner and outer walls being sealed to each other at the first and second ends, forming an annular gap between the inner and outer walls, the first and second ends each being configured for suturing to at least one blood vessel; and a biological agent disposed between the inner and outer

walls for release through the inner wall radially inwardly in a circular fashion at least near the first and second ends for treating suture points joining the at least one blood vessel at the first and second ends", as recited in base Claim 1, as amended, and similarly in base Claim 16, as amended. Therefore, Claims 4 and 18 are in condition for allowance. Reconsideration is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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